Hogan Lovells

Brexit snapshot: Medicines

Do you have a centralised EU marketing authorisation holder, orphan designation holder, manufacturing activities including import, batch control or batch release sites, a Qualified Person for Pharmacovigilance (QPPV), clinical trials, suppliers, CMOs, customers or a contracting party located in the UK?

Brexit will affect you. What should you do now?

What is the latest on Brexit?

The UK is scheduled to leave the EU at 11pm on 29 March 2019.

Currently, the UK is still part of the EU and EU law still applies in the UK. On leaving, the UK will become a "third country".

EU law will be transposed into UK law.

The UK's European Union (Withdrawal) Act will transpose all EU law directly into UK law. Assuming that happens on day one after Brexit, the law in the UK will still be the same as it is currently and the same as in the EU. Post-Brexit, the UK Government can then decide whether it wishes to make changes to that UK legislation.

But it's not that simple in practice.

Transposing over 40 years of legislation is not straightforward. There are numerous references in EU law to a company or person being present within the EU, or the involvement of an EU institution or agency, or access to an EU system or database, which cannot simply be transposed. The UK cannot unilaterally legislate to continue participating in those EU bodies and systems. Depending on the outcome of negotiations with the EU, the UK may need to set up new bodies and systems to enable parts of UK legislation to operate post-Brexit.

The UK and EU have negotiated the withdrawal terms...

The EU27 and UK have negotiated draft terms on which the UK will leave the EU, known as the Withdrawal Agreement. This sets out what will happen to existing products and regulatory requirements in the UK and EU27 on withdrawal. It also provides for a "transition" period after the UK leaves to give businesses time before the new arrangements apply, which would run from 30 March 2019 to 31 December 2020.

...and an outline of the future trading relationship.

The EU operates as a single market with common regulatory standards and a customs union with no tariffs on imports between Member States and a common tariff for imports from "third countries". The UK and EU have also negotiated a political declaration containing a high level outline of the future UK and EU relationship based on a free trade area with zero tariffs and quotas, a new customs arrangement and co-operation on goods. However, there is still much uncertainty as to the details of the future relationship at this stage.

The UK Parliament has rejected the withdrawal terms and outline.

While EU leaders have approved the terms of the Withdrawal Agreement and the political declaration on the future trading relationship, the UK Parliament has voted to reject them. Both the UK and the EU27 have been explicit that nothing is agreed until everything is agreed, which means that without approval of the Withdrawal Agreement and political declaration, the UK risks "crashing out" with no transition arrangements in place.

The likelihood of a "no deal" Brexit has increased

The default legal position is that the UK will leave the EU automatically at 11pm on 29 March 2019 with no "deal" in place, unless something else is agreed. The current political deadlock in the UK is unprecedented so it is difficult to predict what will happen next. The possibilities include trying to amend the existing draft Withdrawal Agreement, negotiating an alternative deal, "no deal", a second referendum or a general election. Many of these options will take time and would likely require the date of Brexit to be delayed. Businesses need to prepare for the real possibility that the UK might leave the EU with no withdrawal terms in place.

To keep up to date with new developments, visit our Brexit hub and subscribe to our Brexit bulletin: **hoganlovells.com/brexit**

The impact of Brexit on medicines

The key areas affected are *regulation, trade, people and innovation*

1

Ensuring the continued supply and safety of medicines is paramount.

While some issues are common across industries, the highly regulated nature of medicines and complex cross-border supply chains means that the impact of Brexit is particularly far-reaching.

2

EU law underpins the UK regulatory framework

Much of the UK's current regulatory framework for medicines is set at EU level and involves EU structures such as the European Medicines Agency (EMA) and EudraVigilance system. Unless mutually agreed by the EU27 and UK, the UK will no longer have access to these EU structures, the EU will not recognise UK regulatory decisions, and the UK MHRA will no longer participate in the EMA's work. The EMA is moving from London to Amsterdam. The UK Government and industry are seeking close co-operation, regulatory alignment and minimal disruption for medicines post-Brexit.

3

Key regulatory risks

Depending on the final agreement reached between the EU and UK, the regulatory implications include:

Marketing authorisations: Centralised EU marketing authorisations (MAs) held by a UK company may need to be transferred to a company in an EU27 Member State and a separate UK MA may be required. National UK MAs granted by the MHRA will remain valid but the MHRA may no longer be recognised in the decentralised and mutual recognition national MA procedures.

Batch control and release: Batch control and release at UK sites and UK based QPPV activities may need to be transferred to an EU27 market.

Clinical trials: UK sponsors of trials conducted in the EU27 may need to appoint a legal representative in an EU27 market. The UK might not participate in the future centralised EU clinical mats authorisation process.

There is also the reciprocal question of whether the UK will recognise EU MAs, EU batch release etc but the UK regulators have indicated they intend to take a pragmatic approach.

4

Key trade risks

The UK is reported to export 540 million patient packs of medicines to the EU27 each year and to import around 440 million packs from the EU27, currently on a zero tariff basis. Any increase in tariffs or non-tariff barriers such as increased processing times at customs resulting from Brexit could significantly disrupt medicine supply chains.

5

Key people and innovation risks

Brexit could impact on the UK's participation in EU research funding and collaboration programmes, as well as EU scientists, researchers and other highly-skilled workers to work in the UK.

Brexit will also impact other relevant areas such as personal data and intellectual property.

For a more detailed analysis of the regulatory issues impacting pharmaceutical companies, read our "First Aid for Pharma" publication: **hoganlovells.com/brexit**

What should you do now to prepare?

For detailed advice on how to identify areas of legal and commercial business risk created by Brexit and contingency planning, visit our Brexit toolkit: **hoganlovellsbrexit.com/brexit-toolkit**

Much about Brexit remains unclear so deciding what changes to make and when is challenging. However what is clear is that you should make sure you have identified potential impacts and have a contingency plan in place so you are in a position to move quickly.

Specifically, pharmaceutical and biotech companies should be:

Reviewing any **regulatory arrangements and supply chain operations** that involve the UK, including marketing authorisations, orphan designations, clinical trials, manufacturing/import sites, testing /batch release, QPPVs and distributors.

Conducting a **gap analysis of any contracts** involving the UK to identify any risk and opportunities created by Brexit and ensure they are aligned with any regulatory changes.

Considering the **wider business impact** of any changes as a result of regulatory requirements. For example any tax or transfer pricing implications or significant IT systems and business process changes of relocating assets or activities to a company in the EU27.

Monitoring Brexit developments and **engaging with government and industry associations in the UK, Brussels and the EU27** to optimize the landscape for your business.

How can we help you?

We can:

Carry out a gap analysis to **identify and prioritise the steps that you should be taking to prepare** for Brexit based on a tailored application of our Brexit toolkit.

Advise you on which **licences and /or operations you need to move** and which EU27 countries you might consider moving them to.

Implement changes to your business ranging from relocating entities, activities or people to IT and other operational changes.

Analyse your contracts to identify and mitigate Brexit related risks in both existing contracts and template agreements to minimise future Brexit risks.

Develop an **effective strategy to engage** with policy makers to support your business priorities.

Train your key stakeholders on the risks and opportunities of Brexit for your business.

Why work with us?

Expertise
Ranked Band 1 by Chambers for Life Sciences in Europe and by Legal 500 for our Brexit advisory work and commercial contracts.

Brexit focus
A dedicated taskforce analysing and alerting businesses to Brexit related issues. Our Brexit Hub covers latest developments and industry specific regulatory analysis.

Policy engagement
Our Chambers Band 1 ranked Public Law and Public Affairs practice is experienced in developing strategies to influence business-critical Brexit policy issues.

International integration
Our integrated cross-border team is experienced in developing practical solutions to pan-European issues.

Experience
We are advising a number of our life sciences clients on their preparations for Brexit.

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